

Pesticide Registration Improvement Extension Act (PRIA 3): Overview of Fee Reduction and Refund Formula

Under PRIA 3, refunds of a portion of the registration service fee are provided following the withdrawal of a PRIA covered application and as a credit for a portion of the Agency's work having been completed prior to October 1, 2012 or with another application. Although refund decisions are made on a case-by-case basis, the Agency intends to use the formulas below as a guide in calculating the amount of any refunds. The formulas were developed based upon the unique review processes within the Antimicrobials Division (**A** fee categories), the Biopesticides and Pollution Prevention Division (**B** fee categories), the Registration Division (**R** fee categories) and the review process for pesticide inert ingredients (**I** fee categories). The formulas take into consideration that 25% of the total fee for each category is non-refundable. Since the Agency retains 25% of the fee, a refund will not be given if a 75% fee waiver or reduction has been granted. For 50% fee waivers and other fee reductions, the formulas will be applied to the remainder of the fee after the 25% of the fee has been subtracted.

Refunds Following a Withdrawal

Pursuant to FIFRA Section 33(b)(8)(a), if an application is withdrawn during the first 60 days after the beginning of the PRIA decision review period, the Agency will refund all but 25% of the registration fee. Refunds for applications withdrawn after the first 60 days of the decision review period will be proportional to the work remaining at the time the action is withdrawn. The maximum that can be refunded is 75%. The Agency will determine the amount of the refund within 90 days after withdrawal and provide any refund as soon as practicable thereafter.

Once withdrawn, any future submission related to the application must be submitted as a new application. It requires either the appropriate full fee (or a portion of the fee (25% or 50%) with a request for a fee waiver for the remainder) or a request for an exemption.

Fee Reduction – Discretionary Refund

Under Section 33(b)(8)(C) of FIFRA, the Agency has discretionary authority to issue a partial refund (up to 75%) of the registration service fee in certain situations. The Agency may refund a portion of a covered registration service fee for one of the following bases: 1) in reviewing the application, the Agency has considered data submitted in support of another pesticide registration application; 2) the Agency has completed portions of the review of the application before the effective date of PRIA 3; or 3) the Agency has rejected the application. Some discretionary refunds are routine and are applied at the time of submission. The second basis listed above may apply for certain applications, for example, new inert approvals, that previously were not subject to pesticide registration service fee but will be after October 1, 2012. For such applications, the applicant may choose to voluntarily pay the pesticide registration service fee and request a discretionary refund based on the amount of work that was completed prior to October 1, 2012. Guidance on refunds may be obtained on the [primary/secondary Web page](#) and by contacting a Registration Ombudsman.

Requests for other reductions in the fee should be discussed with the appropriate [Registration Ombudsman](#). Although refund decisions are made on a case-by-case basis, the Agency intends to use the following formulas as a guide in calculating the amount of these discretionary refunds. Because the Agency must retain 25% of any registration service fee, discretionary refunds will not

be considered if an application's fee has already been reduced by 75% as a result of a small business fee waiver.

Guide to Reading the Tables

The Agency has developed specific tables for each of the three registering divisions within the Office of Pesticide Programs (Antimicrobials Division, Biopesticides and Pollution Prevention Division, and Registration Division) as well as a table for inert ingredient actions. These formulas were developed in collaboration with the three registering divisions and the inert ingredient review program and differ only in ways that reflect the review processes unique to each.

The tasks listed in the tables are the sequential steps in the Agency's review process. Column 1 reflects the task or activity involved in the review process. Column 2 reflects the percentage of work that particular task generally entails for the entire Agency review process. Column 3 reflects, as a general matter, the total percentage of work that the Agency has usually completed if all tasks through that stage in the process are complete. Column 4 is the reciprocal of Column 3 and generally reflects the percentage of work remaining once the Column 3 stage is completed.

For example, if an application to amend a registration to add a new use is withdrawn more than 60 days after the beginning of the PRIA decision review period, and the front end screen, data review, and risk assessment have been completed with only the regulatory decision remaining, as a general matter, the Agency would refund 15% of the application's fee (according to its category). However, if a fee waiver has already been granted, the refund will be reduced by the amount that has already been waived. If a 75% fee waiver was granted with the application, the applicant would not receive a refund since 25% of the fee is non-refundable.

The amount of any fee and information on the type of application covered by the fee may be found on the [Fee Determination Decision Tree](#).

Antimicrobials Division

New Active Ingredients and New Uses

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---------------------------------------|-------------------------|---------------------------|---|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Primary Review | 30% | 55% | 45% |
| Secondary Review | 12% | 67% | 33% |
| Risk Assessment – End point Selection | 18% | 85% | 15% |
| FR Notice,Registration Decision | 15% | 100% | 0 |

* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

New Products and Amendments

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|-----------------------|-------------------------|---------------------------|---|
|-----------------------|-------------------------|---------------------------|---|

| | | | |
|---------------------------------------|-----|------|-----|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Science Reviews | 65% | 90% | 10% |
| Registration Decision | 10% | 100% | 0 |

* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

Biopesticides and Pollution Prevention Division

New Active Ingredients and New Uses

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---|--------------------------------|----------------------------------|--|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Primary Review | 30% | 55% | 45% |
| Secondary Review | 15% | 70% | 30% |
| Risk Assessment | 15% | 85% | 15% |
| BRAD, FR Notice, Registration Decision | 15% | 100% | 0 |

* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

New Products and Amendments

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---------------------------------------|--------------------------------|----------------------------------|--|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Science Reviews | 65% | 90% | 10% |
| Registration Decision | 10% | 100% | 0 |

* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

NOTE: If a data gap or significant deficiency is identified during review of the data/studies which require resubmission of data that need to be reviewed before the risk assessment can be conducted, then it may be determined that only 50 percent of the work is completed. It is anticipated that in such cases renegotiations of decision review periods are likely to be needed.

Registration Division (conventional pesticides)

Whereas the Antimicrobials Division and the Biopesticides and Pollution Prevention Division are interdisciplinary divisions where both the regulatory review and science assessment occur within

self-contained units, the Registration Division utilizes the services of the Environmental Fate and Effects Division (EFED) and the Health Effects Division (HED) to complete science reviews for the majority of registration actions. Therefore, the Registration Division has developed formula for two scenarios: A) where the Registration Division relies upon support from OPP's science divisions and B) where the Registration Division completes both science review and regulatory review within the Registration Division (e.g., New Product–Fast Track, and some Non-Fast-Track Actions).

A) New Active Ingredients, New Uses, and Other Actions Required Review by EFED and HED

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---|-------------------------|---------------------------|---|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Primary Review | 20% | 45% | 55% |
| Secondary Review | 15% | 60% | 40% |
| Risk Assessment | 25% | 85% | 15% |
| FR Notice, Registration Decision | 15% | 100% | 0 |

* Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

NOTE: The science review generally reflects 60 percent of the Agency's review work for a particular registration action for a conventional chemical. The Agency has divided this 60 percentage in half – 30% for review by EFED (environmental/ecological risk assessments) and 30% for review by HED (human health risk assessments). In calculating the progress in completing the registration action, the Agency will generally multiply the percentage of work completed in each division using the table below by 30% in order to document the total percentage of work completed for a particular registration action.

B) Science and Regulatory Reviews Completed for Conventional Applications

| Tasks Completed | EFED | HED |
|----------------------------------|------|------|
| Primary Review | 50% | 40% |
| Secondary Review | 15% | 20% |
| Drinking Water Assessment | 15% | ---- |
| Risk Assessment | 20% | 40% |

New Products and Amendments and Actions RD Completes within the Division

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---------------------------------------|-------------------------|---------------------------|---|
| Non-refundable portion of fee* | 25% | 25% | 75% |

| | | | |
|------------------------------|-----|------|-----|
| Science Reviews | 65% | 90% | 10% |
| Registration Decision | 10% | 100% | 0 |

- * Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen

Inert Ingredients

All Inert Ingredient Approvals/Amendments

| Tasks to Be Completed | Percent of Work by Task | Percent of Work Completed | Percentage Remaining if Item is Completed |
|---------------------------------------|--------------------------------|----------------------------------|--|
| Non-refundable portion of fee* | 25% | 25% | 75% |
| Primary Review | 20% | 45% | 55% |
| Secondary Review | 15% | 60% | 40% |
| Risk Assessment | 25% | 85% | 15% |
| FR Notice, Approval Decision | 15% | 100% | 0 |

- * Includes Front End or In processing, Fee Category Assignment, Dockets, Tracking, OPPIN Financial and Data Entries, Distribution, 21 Day Initial Content Screen